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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,010	02/27/2002	Jason A. Galdonik	293/045 CIP	8588
1473	7590	01/26/2004		
FISH & NEAVE 1251 AVENUE OF THE AMERICAS 50TH FLOOR NEW YORK, NY 10020-1105			EXAMINER ROBERTS, PAUL A	
			ART UNIT 3731	PAPER NUMBER 9

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

AK

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/084,010		GALDONIK ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Paul A Roberts		3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 May 2003.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Shennib 6464709. Shennib et al. discloses a method for inserting the anastomosis device to complete a side-to-side anastomosis. Shennib et al. discloses that this device may be used to construct a surgical bypass (line 22, col. 1.) As shown in figure 2, described in column 9, lines 45-65, and described in column 10, lines 5-20, the method of inserting the Shennib et al. device includes making an aperture in the side wall of the graft vessel and the body vessel as well as making an incision proximal to item 50 in figure 2. The Shennib et al. device is hollow and annular and is inserted between the 1<sup>st</sup> and 3<sup>rd</sup> apertures. The method further includes inserting the first connector through the first and third apertures to form a first hollow annular anastomotic connection between the sidewalls of the graft conduit and the body tissue conduit annularly around the first and third apertures. Looking at figures 7a-7e, the first axial portion (2) is extended from the first aperture into the third aperture. The first axial portion would be shielded by the catheter 40 during an insertion of the Shennib et al. device. During the steps of moving, extending, and inserting, the first axial member is shielded by the catheter. The first axial portion is then unshielded when the implant slides out of the catheter. The Shennib et al. method also includes the step of deforming the first connector thereby causing it to press together the sidewall of the graft conduit annularly and the sidewall of the body tissue conduit

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annularly. Shennib et al. specifies that it may be necessary to annularly enlarge the connector using a balloon, which includes the steps of inflating and deflating the balloon (line 67, column 10.) The balloon would inherently be removed through the first severed, because the balloon cannot be left inside the patient's body. The graft conduit is then tied off as shown by item 50. Furthermore, Shennib et al. discloses the step of closing the graft conduit (65, col. 10.) Shennib et al. does not specifically point out how the bypass surgery would be implemented. He does state that his device is intended to be used for a surgical bypass. Forming a surgical bypass would inherently require the user to make a second aperture in the sidewall of the graft conduit adjacent the severed end and a fourth aperture in a sidewall of the second portion of the body of tissue conduit. The method would further inherently include repeating all of the steps above for installing the first hollow annular connector between the first and third apertures, except the steps would be for the second connector through the second and fourth apertures.

### ***Response to Arguments***

The language in the St. Germain reference render the scope of the claims very clear while the applicant's claim language does not. However, the applicant's claim language is not so obfuscated as to disable one of ordinary skill in the art from understanding the invention or the scope of the claims, therefore, the examiner withdraws the rejection under 112 2<sup>nd</sup> paragraph.

Most the applicant's arguments are moot in view of the new grounds of rejection. However, the arguments regarding the Shennib reference not anticipating an annular, hollow connector still apply. The connector is hollow because it has an opening in the middle of the device (shown in figure 2, item 4.) The connector is also annular because the section is a ring, and that

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ring is annular. The rest of the applicant's arguments with respect to claims 1-15 have been considered but are moot in view of the new ground(s) of rejection above.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A Roberts whose telephone number is (703) 305-7558. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Paul Roberts  
January 16, 2004

  
MICHAEL J. MILANO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700